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EXAMINER	
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1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,518	ELLIOTT ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-91* is/are pending in the application.

4a) Of the above claim(s) *52-61 and 76-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *62-75 and 89-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/07, 3/25/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III (claims 62-75 and 89-91) in the reply filed on 2/23/2010 is acknowledged. The traversal is on the ground(s) that the Group IV claims (78-86) are method of use of the compositions of the Group III claims. While Applicants do not concede that the claims of Groups III and IV represent inventions which are obvious over one another, it is noted that the common, novel technical feature is the use of fully differentiated non-hepatocyte cells that, surprisingly, secrete liver secretory factors, as set forth in the claims as amended.

This is found not persuasive because upon the consideration of new limitation of "differentiated" non-hepatocytes, the technical feature shared by Group III and IV is "differentiated non-hepatocyte cell type including gall bladder epithelial cells." Since the culture of gall bladder epithelial cells is known in the art (as disclosed below; Kobayashi et al.; Lee et al.; Clement et al.), the limitation cannot be considered as a special technical feature. The property directed to the non-hepatocyte cells, particularly gall bladder epithelial cells, is considered to be inherent property of the cells taught by the prior art cited below.

It is also acknowledged that Applicant's election with traverse of gall bladder epithelial cell as an elected species. The traversal is on the ground(s) that the disclosed Markush type species of the non-hepatocyte cells all have the ability to secrete liver secretory factors and these cells are all differentiated, and thus, these cell types should be deemed to form a proper Markush group in that they are unified by this functionality of secreting liver factors and the characteristic of differentiation.

M.P.E.P. §1850 states, "The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted

one for the other, with the expectation that the same intended result would be achieved. The fact that the alternatives of a Markush grouping can be differently classified should not, taken alone, be considered to be justification for a finding of a lack of unity of invention. When dealing with alternatives, if it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention should be reconsidered by the examiner. Reconsideration does not necessarily imply that an objection of lack of unity shall be raised. (See Examples in Chapter 10 of the International Search and Preliminary Examination Guidelines which can be obtained from the Patent Examiner's Toolkit link or from WIPO's web site (www.wipo.int/pct/en/texts/gdlines.htm.))"

The listed species are not known as alternative in the art (endothelial cells vs. epithelial cells; gall bladder cells vs. bile duct cells vs. hepatic vessel cells, sinusoid cells, non-parenchymal liver cells), and a person of ordinary skill in the art would not expect the listed cells behave the same way as claimed in the invention, and thus, they are "recognized class of cells" known in the art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 52-61 and 76-88 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 62-75 and 89-91 have been considered on the merits.

Information Disclosure Statement

The information disclosure statement filed 3/25/2010 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the English translation of Chinese patent application (CN20050017708) did not disclose any publication date of the document. It has been placed in the application file, but the information referred to therein has not been considered as

to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim 91 is objected to because of the following informalities: It should be dependent on the "device" rather than "method".

Claim Objections

Claim 79 is objected to because of the following informalities: The instant claim discloses a Markush-type species. M.P.E.P. §2173.05(h) states "Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 64, 69 and 90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 discloses the phrase "the hepatocyte cells are from immortalized cells in a

commercially available culture." It is not clear whether the hepatocytes are derived from commercially available culture of immortalized cells, the hepatocytes are the immortalized cells or the hepatocytes are immortalized in a commercially available culture medium. Is this limitation directed to the immortalized hepatocyte? Clarification is required. For examination, the limitation is interpreted as "immortalized hepatocytes".

Claim 69 discloses a ratio between gall bladder epithelial cells:hepatocytes. It is not clear whether this ratio is based on the number of cells, or any other parameters (e.g. amount of secretion, etc.). Clarification is required.

Claim 90 discloses a trademark or trade name of "TheraCyte™". M.P.E.P. § 2173.05(u) recites, "It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name." If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982).

Regarding claim 90, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex*

parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 90 recites the broad recitation a capsule device, and the claim also recites a TheraCyte device available from TheraCyte, which is the narrower statement of the limitation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 62-75 and 89-91 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The newly amended limitation of "differentiated" in claim 62 and its dependent claims introduces a new matter to the current application.

In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements

without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen,* 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 62, 66-68 and 70-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (1991, Gastroentelogica Japonica) or Lee et al. (2003, Am J Physiol Gastrointest Liver Physiol).

The instant claim is interpreted as a composition comprising gall bladder epithelial cells.

Kobayashi et al. or Lee et al. teach a culture of human gall bladder epithelial cells (see entire documents).

The limitation directed to the intended use of the composition for implantation, this does

not provide any structural limitation to the claimed product, and thus, does not provide any weight in determining patentability. M.P.E.P. § 2111.02 reads, "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "implantable" or "upon implantation into a recipient" does not affect the patentability of the claimed composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

With regard to the limitation directed to the intended results of "capable of secreting one or more liver secretory factors or of providing one or more liver metabolic and/or physiologic functions", it is expected that the gall bladder epithelial cell culture of Kobayashi et al. or Lee et al. would have the same property as the claimed composition. Furthermore, this property is claimed only when the composition is implanted to a recipient, and thus, the composition per se does not need the property. Nevertheless, since the references teach the same cells as the claimed composition, they would have the same property upon the intended use of implantation.

With regard to the limitations of claims 70-74, these limitations are directed to the property of the composition comprising gall bladder epithelial cells. Since the composition (co-culture) of Clement et al. comprises the same components of gall bladder epithelial cells as claimed in the current invention, it is considered that the gall bladder epithelial cells of Clement et al. possess the same property.

M.P.E.P. §2112 states that "The discovery of a previously unappreciated property of a

prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. *v.* Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re* Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re* Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Thus, the reference anticipates the claimed subject matter.

Claims 62, 63, 66-68, 70-75 and 89 are rejected under 35 U.S.C. 102(b) as being anticipated by Clement et al. (1984, Hepatology).

The instant claims are interpreted as a composition comprising human gall bladder epithelial cells and hepatocytes.

Clement et al. teach a co-culture system comprising hepatocyte and human gallbladder epithelial cells (p.374, last par. of left col. through 1st par. of right col.).

The limitation directed to the intended use of the composition for implantation, this does not provide any structural limitation to the claimed product, and thus, does not provide any weight in determining patentability. M.P.E.P. § 2111.02 reads, "If the body of a claim fully and

intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." As such, the limitation "implantable" or "upon implantation into a recipient" does not affect the patentability of the claimed composition. Compositions are defined by their physical, structural, and chemical properties, not by an intended use or application.

With regard to the limitation directed to the intended results of "capable of secreting one or more liver secretory factors or of providing one or more liver metabolic and/or physiologic functions", it is expected that the co-culture system of gall bladder epithelial cells and hepatocytes of Clement et al. would have the same property as the claimed composition. Furthermore, this property is claimed only when the composition is implanted to a recipient, and thus, the composition per se does not need the property. Nevertheless, since the references teach the same cells as the claimed composition, they would have the same property upon the intended use of implantation.

With regard to the limitations of claims 70-74, these limitations are directed to the property of the composition comprising gall bladder epithelial cells. Since the composition (co-culture) of Clement et al. comprises the same components of gall bladder epithelial cells as claimed in the current invention, it is considered that the gall bladder epithelial cells of Clement et al. possess the same property.

The limitation of claim 89 is interpreted as the composition of gall bladder epithelial cells since there is no structural limitation directed to the device other than the composition of gall

bladder epithelial cells.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 62-75, 89 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement et al. (supra) in view of Kobayashi et al. (2001, Addition Biology; Abstract only).

Clement et al. teach the limitations of claims 62, 63, 66-68, 70-75 and 89 (see above).

With regard to the limitation of claim 64 and 91, it is interpreted that the hepatocytes are immortalized.

Although Clement et al. do not teach the hepatocyte cells are immortalized, it is well known in the art that cell lines (immortalized cells) can replace the use of primary cells in various application. For example, Kobayashi et al. teach that a reversibly immortalized hepatocyte cell lines can replace the use of primary hepatocyte cultures since the hepatocyte cell lines can provide the advantages of unlimited availability, sterility and uniformity (see abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to replace the primary hepatocyte of Clement et al. with the immortalized hepatocyte cell line taught by Kobayashi et al.

Whether or not the hepatocytes are derived, isolated or obtained from any commercial

source, this does not provide any structural limitation to the claimed composition, and thus, not considered as a limiting factor.

With regard to the limitation directed to the non-hepatocyte cell type (gall bladder epithelial cells) is a neonatal cell (claim 65), Clement et al. in view of Kobayashi et al. do not teach the limitation. However, it would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try gall bladder epithelial cells obtainable from neonatal sources. This is because it is considered that the choice of neonatal source for the gall bladder epithelial cells is an obvious selection from the finite number of identified sources for the gall bladder epithelial cells.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

With regard to the ratio of hepatocyte: gall bladder epithelial cells (claim 69), this limitation is considered to be optimized by routine experimentation. It is well settled that routine optimization is not patentable, even if it results in significant improvements over the prior art. In support of this position, attention is directed to the decision in *In re* Aller, Lacey, and Haft, 105

USPQ 233 (CCPA 1955): Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. Under some circumstances, however, changes such as these may impart patentability to a process if the particular ranges claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art. *In re* Dreyfus, 22 C.C.P.A. (Patents) 830, 73 F.2d 931,24 USPQ 52; *In re* Waite et al., 35 C.C.P.A. (Patents) 1117, 168 F.2d 104, 77 USPQ 586. Such ranges are termed "critical" ranges, and the applicant has the burden of proving such criticality. *In re* Swenson et al., 30 C.C.P.A. (Patents) 809, 132 F.2d 1020, 56 USPQ 372; *In re* Scherl, 33 C.C.P.A. (Patents) 1193, 156 F.2d 72, 70 USPQ 204. However, even though applicant's modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art. *In re* Sola, 22 C.C.P.A. (Patents) 1313, 77 F.2d 627, 25 USPQ 433; *In re* Normann et al., 32 C.C.P.A. (Patents) 1248, 150 F.2d 708, 66 USPQ 308; *In re* Irmscher, 32 C.C.P.A. (Patents) 1259, 150 F.2d 705, 66 USPQ 314. More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re* Swain et al., 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D. C. 324, 135 F.2d 11,57 USPQ 136. (Emphasis added). With regards to determining experimental parameters, such as time in culture, the court has held that "[d]iscovery of optimum value of result effective variable in known process is ordinarily within skill of art (In re Boesch and Slaney, 205 USPQ 215 (CCPA 1980)).

The adjustment of particular conventional working conditions (e.g., ratio) is deemed

merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited reference before him/her.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed. Claim 90 is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Primary Examiner, Art Unit 1651